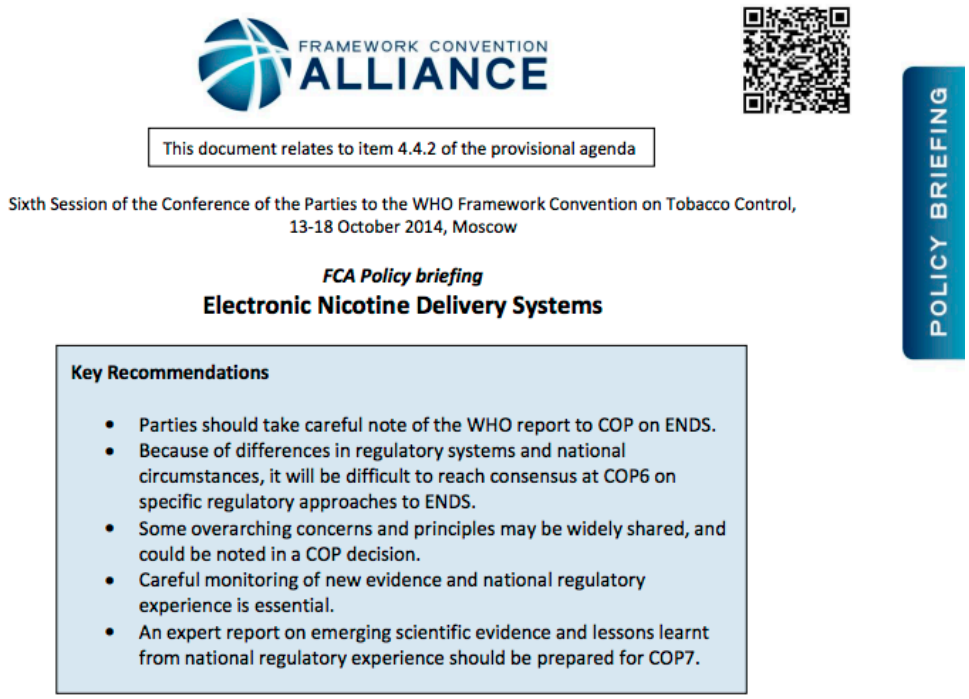
Review of the FCA COP-6 position on e-cigarettes



FRAMEWORK CONVENTION ALLIANCE

This document relates to item 4.4.2 of the provisional agenda

Sixth Session of the Conference of the Parties to the WHO Framework Convention on Tobacco Control, 13-18 October 2014, Moscow

FCA Policy briefing

Electronic Nicotine Delivery Systems

POLICY BRIEFING

Key Recommendations

- Parties should take careful note of the WHO report to COP on ENDS.
- Because of differences in regulatory systems and national circumstances, it will be difficult to reach consensus at COP6 on specific regulatory approaches to ENDS.
- Some overarching concerns and principles may be widely shared, and could be noted in a COP decision.
- Careful monitoring of new evidence and national regulatory experience is essential.
- An expert report on emerging scientific evidence and lessons learnt from national regulatory experience should be prepared for COP7.

Not bad. But good enough?

On 7 October 2014, the Framework Convention Alliance, the largest alliance of NGOs that attend and lobby in the WHO FCTC meetings, published its COP-6 policy brief on ENDS (e-cigarettes). Its policy briefing sets out a position that reflects a careful navigation through the middle ground between the pro- and anti- harm reduction factions in that alliance, while basically not saying too much that is wrong or likely to cause harm. It is a real achievement that they reached agreement at all, given how polarising this issue is within that community. The paper is a positive contribution to the negotiations and important corrective to the stance taken by WHO. Some more thoughts:

- Their position is in sharp contrast to WHO, which failed to achieve similar balance itself in its own paper and communications. The maturity of the NGO approach should put WHO to shame and on notice that it must do better in future.
- The argument that it is 'not feasible or advisable' for COP to come to a regulatory position is right and constructive given the

developing evidence and poor understanding of what is already known – especially in that world. It contrasts favourably with the hubris of WHO in simply listing measures without analysis, justification or assessment and expecting Parties to adopt them.

- The idea of agreeing on direction-setting principles is a good one: I recommend this as a prior requirement for any policy making. Their FCA principles are not bad, and much better than the one sided loss-averse principles proposed by WHO. The FCA principles listed below and discussed in more detail in the next section.

1. *The global burden of death and disease from tobacco is primarily caused by smoking.*
2. *While quitting tobacco use is paramount, quitting nicotine use altogether is the best option.*
3. *For those unable to quit tobacco, switching to alternative sources of nicotine that are less harmful can reduce, often very substantially, the harm smoking causes to the individual.*
4. *The benefits of such an approach would be maximised if uptake were limited to existing smokers who are unable to quit.*
5. *The risks of such an approach would be minimised by taking measures to limit uptake by never-smokers, in particular amongst young people, to protect non-users, and to discourage long-term dual use.*
6. *There could be negative unintended consequences from over-regulation just as there could be from under-regulation.*
7. *The involvement of tobacco companies in the production and marketing of e-cigarettes is a matter of particular concern as there is an irreconcilable conflict of interest between those profiting from the sale of tobacco and public health.*

- They are right in their analysis that different weight is placed on the different principles in their list by the various factions in the debate, but that is partly where the problem lies with this alliance.
- The idea of setting up an expert body is good, providing that the membership is not stitched up to give pre-ordained answers. In other words, WHO or the FCTC secretariat shouldn't be allowed to do what it does with science and hand-pick extremists to give it the answers that

best support its prejudices.

- They wish to include civil society in their expert body. In that world, the definition of 'civil society' usually means: "*that's us, we the FCA are civil society*". In fact, they are not – but it's a longer discussion about who they are, what they represent and to whom they owe their involvement. But as a *minimum*, they should have representatives of the users of these products involved – not only for the knowledge and experience they would bring but also on the 'nothing about us, without us' principle that is routinely and complacently ignored in this forum.
- The habit of excluding representatives of producers is a bad one – and partly responsible for NGOs promoting very burdensome regulatory regimes, thus unwittingly supporting the tobacco industry's preferred approach. A risk that is mercifully recognised at principle 6.

Comments on the FCA's principles

1. The global burden of death and disease from tobacco is primarily caused by smoking

Comment: Yes, the burden of disease is primarily caused by *smoking.* The FCA should adopt similar open-minded principles with respect to other non-combustible recreational nicotine products that provide orders of magnitude lower risk – that would include smokeless tobacco products (appropriately regulated) and vapourising 'heat not burn' tobacco products. It is time to acknowledge that bans on products like snus have no scientific or ethical basis and cause harm. Targets for reducing tobacco consumption should be focussed on smoking, or at least be weighted by disease risk. We should stop conflating the harms caused by betel, areca and lime in South Asian products with smokeless tobacco.

2. While quitting tobacco use is paramount, quitting nicotine use altogether is the best option

Comment: From a health point of view, quitting *smoking* is paramount (see principle 1) not tobacco use. Quitting nicotine is not necessarily the best option if it leaves permanent craving, a sense of loss and risk of relapse back to smoking. The big step is taken when someone quits smoking – at that point, their job is done. Even if you agree the quitting nicotine is the 'best option' it is important to

be clear how far you would go to cause it to happen – for example, would it be friendly advice, or would you try to back that preference with an element of coercion – for example by taxing nicotine? I do not think the latter is justified.

3. For those unable to quit tobacco, switching to alternative sources of nicotine that are less harmful can reduce, often very substantially, the harm smoking causes to the individual

Comment: This is the key point – only it should say unable *or unwilling* – people are, surely at least partly, autonomous agents who take their own decisions about risk. There is a strong ethical justification for allowing and encouraging people to make these choices for themselves. Much of conventional tobacco control creates pressure and motivation to quit smoking, but conventional tobacco control has been poor at recognising transitional pathways that appeal to smokers, rather than the preferred course of the medical profession or regulators.

4. The benefits of such an approach would be maximised if uptake were limited to existing smokers who are unable to quit

Comment: This sounds reasonable but is *not true*. Alternative sources of nicotine also have the prospect of substituting for smoking initiation in current non-smokers. One of the reasons for very low rates of smoking in parts of Scandinavia is that snus initiation has displaced smoking. It is possible alternative nicotine sources them to have a 'protective' effect by diverting young people away from smoking into something that does little harm and is less likely to form dependence. While this pathway is not as desirable as remaining as a permanent non-smoker, it is better than smoking initiation. It is also possible that uptake by ex-smokers works as a protective effect against relapse to smoking.

5. The risks of such an approach would be minimised by taking measures to limit uptake by never-smokers, in particular amongst young people, to protect non-users, and to discourage long-term dual use

Comment: The question, acknowledged but not addressed in the briefing, is how to strike the trade-offs between measures that limit uptake, protect bystanders, and discourage long-term dual use (if this is an alternative to quitting) and encouraging smokers to switch to alternative nicotine products. What if a measure designed to reduce unintended consequences (e.g. banning certain flavours or types of advertising has the effect of reducing the number of smokers

who quit). In other words, the third principle is in tension with the fourth and fifth. Some subsidiary principles might help:

a. Take a realistic evidence based view of the *scale* of these unintended consequences (extremely low at present) and the *harm* they would cause to individuals (extremely low unless they progress to smoking). Further, recognise that some ENDS use is an alternative to smoking in never smokers and young people: that it may be protecting non-users from smoke (especially in the home); and that long-term dual use only *adds* to the problem if it is alternative to quitting in the dual user.

b. Take an evidence-based view of the harms avoided if people switch or cut down substantially (these are very large – both to the individual and to bystanders)

c. Weigh the avoided harms against the unintended consequences, but also apply a 'tolerability of risk' lens and recognise that zero risk is not and never has been an aim for adults or adolescents.

6.There could be negative unintended consequences from over-regulation just as there could be from under-regulation

Comment: Possibly the most important insight of the paper and discussed here: *Turning the tables on public health – let's talk about the risks they create*. A double negative is at work – 'tough on alternatives to smoking' can mean 'easy on smoking'. The trick is to find a 'sweet spot' for regulation that builds consumer confidence, gets rid of cowboys, protects against most of the risk, but allows sustains the appeal of the product, pace of innovation and cost advantages. I think it is becoming clear to the more thoughtful people in tobacco control that pressing for very strong regulation leaves them in an unholy (if unwitting) alliance with the more cynical tobacco companies, who wish to use regulatory barriers to entry to destroy competitors, limit the potential of ENDS category and shape the market to suit the commoditised, high volume, low diversity products that best suit their business model.

7. The involvement of tobacco companies in the production and marketing of e-cigarettes is a matter of particular concern as there is an irreconcilable conflict of interest between those profiting from the sale of tobacco and public health.

Comment: This is not really a useful principle in its current form – though it is a bit of a mantra and to be expected from this alliance. If it turns out that 'harm reduction' is good for health, as the preceding six principles suggest it may well be, then there it is problematic to deny this as a matter of principle if the products happen to be made by tobacco companies or their subsidiaries. It should be problematic *only if their involvement results in more smoking*. It is very far from clear that the companies have incentives to protect smoking (a longer discussion, but competition for market share will tend to prevent this and excessive regulation will encourage it). I would prefer:

> *Regulation of the market for e-cigarettes should not have the aim or effect of either: protecting cigarette sales; or favouring the e-cigarette products of tobacco manufacturers relative to independent or smaller scale producers.*

Overall – good, but good enough?

This paper is good and a welcome and constructive development – and the architects of it should take credit where credit is due. But is it good enough? I don't want to be churlish, but…

…this alliance really should be the pre-eminent civil society forum in the world for addressing the harms arising from tobacco use. Alliance members should not be cheerleading populist prohibitionist stances (as some do), but leading with real insight and helping to make the political headroom for measures that may seem counter-intuitive or difficult, but deliver major health dividends – tobacco harm reduction falls into this category. It should be taking an evidence-based and ethically-principled view of the issues, and not allowing the instinctive preferences and prejudices of some of its members to cloud its collective judgement and fudge its positions My concern is that that this paper looks like a *middle ground* between a more-or-less rigorous approach and the fears and fictions that are generated in the tobacco control community more broadly.

Rather than be grateful that the position is not far worse (which of course I am) perhaps we should lament that it is not *far better*? Think what could be achieved if this alliance embraced the concept of tobacco harm reduction, and ran hard with it – becoming the experts and authorities on managing the risks and unintended consequences in their own countries and, if appropriate, in the FCTC.

The only conceivable way I can see to meet the extremely ambitious commitment to reduce tobacco consumption* by the 30% by 2025 is to find alternatives that make it easier for smokers to quit smoking. There are 10 years of innovation in ENDS/harm reduction technologies to come before 2025, how can the benefits be harnessed, especially in developing countries, and the risks are properly placed in proportion and managed? If the lives of FCA members depended on hitting that 30% goal, would *any of them* take a hostile approach to e-cigarettes? I doubt it. But many millions of people's health, wellbeing and life expectancy will actually depend on it.

* the target should be smoking or tobacco consumption weighted by disease risk. It is counter-productive to have an undifferentiated target that includes both smokeless tobacco and smoking when the former is an alternative to the latter but at greatly reduced disease risk.

Debate

If you disagree with this or think I have misunderstood, especially if you are in the FCA, I would really welcome a debate. Use the comments or, if you would like to do it privately, use email or the contact page .